



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 April 2016
EMA/285396/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: influenza vaccine (split virion, inactivated, prepared in cell cultures)

Procedure no.: PSUSA/00010299/201508



Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Preflucel 2012/2013, suspensie voor injectie 0,5 ml Griepvaccin (gesplitst virion, geïnactiveerd, bereid in celculturen)	AT/H/0253/001	RVG 108793	BAXTER B.V.	NL
PREFLUCEL Influenzavaccine (inaktiveret, split virion, dyrket i cellekulturer)	AT/H/0253/001	47867	BAXTER A/S	DK
PREFLUCEL Injekční suspenze v předplněné injekční stříkacce Vakcína proti chripce (Štepený virion, inaktivovaná, připravovaná na bunecných kulturách)	AT/H/0253/001	59/772/10-C	BAXTER AG.	CZ
Preflucel injeksjonsvæske, suspensjon i ferdigfylt sprøyte Vaksine mot influensa (inaktivert, splittvirus, fremstilt i cellekultur)	AT/H/0253/001	10-8003	BAXTER AS	NO
Preflucel injektioneste, suspensio, esitäytetyssä ruiskussa Influenssarokote (soluissa tuotettu inaktivoitu osavirusrokote)	AT/H/0253/001	29303	BAXTER OY	FI
PREFLUCEL Injektionssuspension in einer Fertigspritze Influenza-Impfstoff (Spaltimpfstoff, inaktiviert, in Zellkulturen hergestellt)	AT/H/0253/001	PEI.H.11496.01.1	BAXTER DEUTSCHLAND GMBH.	DE

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PREFLUCEL Injektionssuspension in einer Fertigspritze Influenza-Impfstoff (Spaltimpfstoff, inaktiviert, in Zellkulturen hergestellt)	AT/H/0253/001	2-00373	BAXTER AG.	AT
PREFLUCEL Injektionssuspension in einer Fertigspritze.	AT/H/0253/001	BE393556	BAXTER SA	BE
Preflucel injektionsvätska, suspension i förfylld spruta Vaccin mot influensa (spjälkat virus, inaktiverat, tillverkat i cellkultur)	AT/H/0253/001	45349	BAXTER MEDICAL AB	SE
PREFLUCEL sospensione iniettabile in siringa prerimpita Vaccino influenzale (virus split, inattivato, preparato in colture cellulari)	AT/H/0253/001	040490031	BAXTER S.P.A.	IT
PREFLUCEL sospensione iniettabile in siringa prerimpita Vaccino influenzale (virus split, inattivato, preparato in colture cellulari)	AT/H/0253/001	040490043	BAXTER S.P.A.	IT
PREFLUCEL sospensione iniettabile in siringa prerimpita Vaccino influenzale (virus split, inattivato, preparato in colture cellulari)	AT/H/0253/001	40490017	BAXTER S.P.A.	IT
PREFLUCEL sospensione iniettabile in siringa	AT/H/0253/001	40490029	BAXTER S.P.A.	IT

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preiempita Vaccino influenzale (virus split, inattivato, preparato in colture cellulari)				
PREFLUCEL Suspensão injectável em seringa pré-cheia Vacina contra a gripe (virião fragmentado, inactivo, preparado em culturas de células)	AT/H/0253/001	5380415	BAXTER MÉDICO-FARMACÊUTICA, LDA.	PT
PREFLUCEL Suspensão injectável em seringa pré-cheia Vacina contra a gripe (virião fragmentado, inactivo, preparado em culturas de células)	AT/H/0253/001	5380407	BAXTER MÉDICO-FARMACÊUTICA, LDA.	PT
PREFLUCEL suspensie voor injectie in een voorgevulde spuit Griepvaccin (gesplitst virion, geïnactiveerd, bereid in celculturen)	AT/H/0253/001	BE393556	BAXTER SA	BE
PREFLUCEL Suspension for injection in a pre-filled syringe Influenza Vaccine (split virion, inactivated, prepared in cell cultures)	AT/H/0253/001	PA 167/142/001	BAXTER HEALTHCARE LTD.	IE
PREFLUCEL Suspension for injection in a pre-filled syringe Influenza Vaccine (split virion, inactivated, prepared in cell cultures)	AT/H/0253/001	PL 00116/0654	BAXTER HEALTHCARE LTD.	UK

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
PREFLUCEL suspension injectable en seringue préremplie Vaccin grippal (virus fragmenté inactivé, préparé à partir de cultures cellulaires)	AT/H/0253/001	BE393556	BAXTER SA	BE
Preflucel Suspensión inyectable en jeringa precargada Vacuna antigripal (virus fraccionados, inactivados, producidos en cultivos celulares)	AT/H/0253/001	73602	BAXTER, S.L.	ES
PREFLUCEL, zawiesina do wstrzykiwan w ampulko-strzykawce Szczepionka przeciw grypie (rozszczepiony wirion), inaktywowana, przygotowana w hodowlach komórek	AT/H/0253/001	18259	BAXTER POLSKA SP Z O.O.	PL